

Amendment to the Claims

The following listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1-33. (Cancelled)

34. (Currently amended) A composition comprising:

~~dead *E. coli* having encapsulated therein a recombinant version of an allergen protein, comprising at least one modified allergen whose amino acid sequence is identical to that of a wild-type allergen, except that the modified allergen has at least one mutation in an IgE site such that the modified allergen has a reduced ability to bind to or cross-link IgE as compared with the wild-type allergen, wherein the modified allergen is encapsulated inside the dead *E. coli*, wherein the wild-type protein-allergen protein is selected from the group consisting of:~~

Ambrosia artemisiifolia (short ragweed) antigen E (Amb a 1);

Ambrosia artemisiifolia (short ragweed) antigen K (Amb a 2);

Ambrosia artemisiifolia (short ragweed) Ra3 antigen (Amb a 3);

Ambrosia artemisiifolia (short ragweed) Ra5 antigen (Amb a 5);

Ambrosia artemisiifolia (short ragweed) Ra6 antigen (Amb a 6);

Ambrosia artemisiifolia (short ragweed) Ra7 antigen (Amb a 7);

Ambrosia trifida (giant ragweed) Ra5G antigen (Amb t 5);

Artemisia vulgaris (mugwort) antigen (Art v 1);

Artemisia vulgaris (mugwort) antigen (Art v 2);

Helianthus annuus (sunflower) antigen (Hel a 1);

Helianthus annuus (sunflower) profilin (Hel a 2);

Mercurialis annua (annual mercury) profilin (Mer a 1);

Cynodon dactylon (Bermuda grass) antigen (Cyn d 1);

Cynodon dactylon (Bermuda grass) antigen (Cyn d 7);

Cynodon dactylon (Bermuda grass) profilin (Cyn d 12);

Dactylis glomerata (orchard grass) AgDg1 antigen (Dac g 1);

Dactylis glomerata (orchard grass) antigen (Dac g 2);
Dactylis glomerata (orchard grass) antigen (Dac g 3);
Dactylis glomerata (orchard grass) antigen (Dac g 5);
Holcus lanatus (velvet grass) antigen (Hol l 1);
Lolium perenne (rye grass) group I antigen (Lol p 1);
Lolium perenne (rye grass) group II antigen (Lol p 2);
Lolium perenne (rye grass) group III antigen (Lol p 3);
Lolium perenne (rye grass) group IX antigen (Lol p 5);
Lolium perenne (rye grass) antigen (Lol p 1b);
Lolium perenne (rye grass) trypsin (Lol p 11);
Phalaris aquatica (canary grass) antigen (Pha a 1);
Phleum pratense (timothy grass) antigen (Phl p 1);
Phleum pratense (timothy grass) antigen (Phl p 2);
Phleum pratense (timothy grass) antigen (Phl p 4);
Phleum pratense (timothy grass) antigen Ag 25 (Phl p 5);
Phleum pratense (timothy grass) antigen (Phl p 6);
Phleum pratense (timothy grass) profilin (Phl p 12);
Phleum pratense (timothy grass) polygalacturonase (Phl p 13);
Poa pratensis (Kentucky blue grass) group I antigen (Poa p 1);
Poa pratensis (Kentucky blue grass) antigen (Poa p 5);
Sorghum halepense (Johnson grass) antigen (Sor h 1);
Alnus glutinosa (alder) antigen (Aln g 1);
Betula verrucosa (birch) antigen (Bet v 1);
Betula verrucosa (birch) profilin (Bet v 2);
Betula verrucosa (birch) antigen (Bet v 3);
Betula verrucosa (birch) antigen (Bet v 4);
Betula verrucosa (birch) isoflavone reductase homologue (Bet v 5);
Betula verrucosa (birch) cyclophilin (Bet v 7);
Carpinus betulus (hornbeam) antigen (Car b 1);
Castanea sativa (chestnut) Bet v 1 homologue (Cas s 1);
Castanea sativa (chestnut) chitinase (Cas s 5);

Corylus avellana (hazel) antigen (Cor a 1);
Quercus alba (white oak) antigen (Que a 1);
Cryptomeria japonica (sugi) antigen (Cry j 1);
Cryptomeria japonica (sugi) antigen (Cry j 2);
Juniperus ashei (mountain cedar) antigen (Jun a 1);
Juniperus ashei (mountain cedar) antigen (Jun a 3);
Juniperus oxycedrus (prickly juniper) calmodulin-like antigen (Jun o 2);
Juniperus sabina (mountain cedar) antigen (Jun s 1);
Juniperus virginiana (eastern red cedar) antigen (Jun v 1);
Fraxinus excelsior (ash) antigen (Fra c 1);
Ligustrum vulgare (privet) antigen (Lig v 1);
Olea europaea (olive) antigen (Ole e 1);
Olea europaea (olive) profilin (Ole e 2);
Olea europaea (olive) antigen (Ole e 3);
Olea europaea (olive) antigen (Ole e 4);
Olea europaea (olive) superoxide dismutase (Ole e 5);
Olea europaea (olive) antigen (Ole e 6);
Syringa vulgaris (lilac) antigen (Syr v 1);
Acarus siro (mite) fatty acid-binding protein (Aca s 13);
Blomia tropicalis (mite) antigen (Blo t 5);
Blomia tropicalis (mite) Bt11a antigen (Blo t 12);
Blomia tropicalis (mite) Bt6 fatty acid-binding protein (Blo t);
Dermatophagoïdes pteronyssinus (mite) antigen P1 (Der p 1);
Dermatophagoïdes pteronyssinus (mite) antigen (Der p 2);
Dermatophagoïdes pteronyssinus (mite) trypsin (Der p 3);
Dermatophagoïdes pteronyssinus (mite) amylase (Der p 4);
Dermatophagoïdes pteronyssinus (mite) antigen (Der p 5);
Dermatophagoïdes pteronyssinus (mite) chymotrypsin (Der p 6);
Dermatophagoïdes pteronyssinus (mite) antigen (Der p 7);
Dermatophagoïdes pteronyssinus (mite) glutathione transferase (Der p 8);
Dermatophagoïdes pteronyssinus (mite) collagenolytic serine prot. (Der p 9);

Dermatophagooides pteronyssinus (mite) tropomyosin (Der p 10);
Dermatophagooides pteronyssinus (mite) apolipophorin like p (Der p 14);
Dermatophagooides microceras (mite) antigen (Der m 1);
Dermatophagooides farinae (mite) antigen (Der f 1);
Dermatophagooides farinae (mite) antigen (Der f 2);
Dermatophagooides farinae (mite) antigen (Der f 3);
Dermatophagooides farinae (mite) tropomyosin (Der f 10);
Dermatophagooides farinae (mite) paramyosin (Der f 11);
Dermatophagooides farinae (mite) Mag 3, apolipophorin (Der f 14);
Euroglyphus maynei (mite) apolipophorin (Eur m 14);
Lepidoglyphus destructor (storage mite) antigen (Lep d 2.0101);
Lepidoglyphus destructor (storage mite) antigen (Lep d 2.0102);
Bos domesticus (cow) Ag3, lipocalin (Bos d 2);
Bos domesticus (cow) alpha-lactalbumin (Bos d 4);
Bos domesticus (cow) beta-lactalbumin (Bos d 5);
Bos domesticus (cow) serum albumin (Bos d 6);
Bos domesticus (cow) immunoglobulin (Bos d 7);
Bos domesticus (cow) casein (Bos d 8);
Canis familiaris (dog) antigen (Can f 1);
Canis familiaris (dog) antigen (Can f 2);
Canis familiaris (dog) albumin (Can f ?);
Equus caballus (horse) lipocalin (Equ c 1);
Equus caballus (horse) lipocalin (Equ c 2);
Felis domesticus (cat) cat-l antigen (Fel d 1);
Mus musculus (mouse) MUP antigen (Mus m 1);
Rattus norvegicus (rat) antigen (Rat n 1);
Alternaria alternata (fungus) antigen (Alt a 1);
Alternaria alternata (fungus) antigen (Alt a 2);
Alternaria alternata (fungus) heat shock protein (Alt a 3);
Alternaria alternata (fungus) ribosomal protein (Alt a 6);
Alternaria alternata (fungus) YCP4 protein (Alt a 7);

Alternaria alternata (fungus) aldehyde dehydrogenase (Alt a 10);
Alternaria alternata (fungus) enloase (Alt a 11);
Alternaria alternata (fungus) acid. ribosomal protein P1 (Alt a 12);
Cladosporium herbarum (fungus) antigen (Cla h 1);
Cladosporium herbarum (fungus) antigen (Cla h 2);
Cladosporium herbarum (fungus) aldehyde dehydrogenase (Cla h 3);
Cladosporium herbarum (fungus) ribosomal protein;
Cladosporium herbarum (fungus) YCP4 protein (Cla h 5);
Cladosporium herbarum (fungus) enolase (Cla h 6);
Cladosporium herbarum (fungus) acid. ribosomal protein P1 (Cla h 12);
Aspergillus flavus (fungus) alkaline serine proteinase (Asp f1 13);
Aspergillus Fumigatus (fungus) antigen (Asp f 1);
Aspergillus Fumigatus (fungus) antigen (Asp f 2);
Aspergillus Fumigatus (fungus) peroxisomal protein (Asp f 3);
Aspergillus Fumigatus (fungus) antigen (Asp f 4);
Aspergillus Fumigatus (fungus) metalloprotease (Asp f 5);
Aspergillus Fumigatus (fungus) Mn superoxide dismutase (Asp f 6);
Aspergillus Fumigatus (fungus) antigen (Asp f 7);
Aspergillus Fumigatus (fungus) ribosomal protein P2 (Asp f 8);
Aspergillus Fumigatus (fungus) antigen (Asp f 9);
Aspergillus Fumigatus (fungus) aspartic protease (Asp f 10);
Aspergillus Fumigatus (fungus) peptidyl-prolyl isomerase (Asp f 11);
Aspergillus Fumigatus (fungus) heat shock protein P70 (Asp f 12);
Aspergillus Fumigatus (fungus) alkaline serine proteinase (Asp f 13);
Aspergillus Fumigatus (fungus) antigen (Asp f 15);
Aspergillus Fumigatus (fungus) antigen (Asp f 16);
Aspergillus Fumigatus (fungus) antigen (Asp f 17);
Aspergillus Fumigatus (fungus) vacuolar serine (Asp f 18);
Aspergillus niger (fungus) beta-xylosidase (Asp n 14);
Aspergillus niger (fungus) antigen (Asp n 18);
Aspergillus niger (fungus) vacuolar serine proteinase;

Aspergillus oryzae (fungus) TAKA-amylase A (Asp o 2);
Aspergillus oryzae (fungus) alkaline serine proteinase (Asp o 13);
Penicillium brevicompactum (fungus) alkaline serine proteinase (Pen b 13);
Penicillium citrinum (fungus) heat shock protein P70 (Pen c 1);
Penicillium citrinum (fungus) peroxisomal membrane protein (Pen c 3);
Penicillium citrinum (fungus) alkaline serine proteinase (Pen c 13);
Penicillium notatum (fungus) N-acetyl glucosaminidase (Pen n 1);
Penicillium notatum (fungus) alkaline serine proteinase (Pen n 13);
Penicillium notatum (fungus) vacuolar serine proteinase (Pen n 18);
Penicillium oxalicum (fungus) vacuolar serine proteinase (Pen o 18);
Trichophyton rubrum (fungus) antigen (Tri r 2);
Trichophyton rubrum (fungus) serine protease (Tri r 4);
Trichophyton tonsurans (fungus) antigen (Tri t 1);
Trichophyton tonsurans (fungus) serine protease (Tri t 4);
Candida albicans (fungus) antigen (Cand a 1);
Candida boidinii (fungus) antigen (Cand b 2);
Malassezia furfur (fungus) antigen (Mal f 1);
Malassezia furfur (fungus) MF1 peroxisomal membrane protein (Mal f 2);
Malassezia furfur (fungus) MF2 peroxisomal membrane protein (Mal f 3);
Malassezia furfur (fungus) antigen (Mal f 4);
Malassezia furfur (fungus) antigen (Mal f 5);
Malassezia furfur (fungus) cyclophilin homologue (Mal f 6);
Psilocybe cubensis (fungus) antigen (Psi c 1);
Psilocybe cubensis (fungus) cyclophilin (Psi c 2);
Coprinus comatus (shaggy cap) antigen (Cop c 1);
Coprinus comatus (shaggy cap) antigen (Cop c 2);
Coprinus comatus (shaggy cap) antigen (Cop c 3);
Coprinus comatus (shaggy cap) antigen (Cop c 5);
Coprinus comatus (shaggy cap) antigen (Cop c 7);
Aedes aegyptii (mosquito) apyrase (Aed a 1);
Aedes aegyptii (mosquito) antigen (Aed a 2);

Apis mellifera (honey bee) phospholipase A2 (Api m 1);
Apis mellifera (honey bee) hyaluronidase (Api m 2);
Apis mellifera (honey bee) melittin (Api m 4);
Apis mellifera (honey bee) antigen (Api m 6);
Bombus pennsylvanicus (bumble bee) phospholipase (Bom p 1);
Bombus pennsylvanicus (bumble bee) protease (Bom p 4);
Blattella germanica (German cockroach) Bd90k (Bla g 1);
Blattella germanica (German cockroach) aspartic protease (Bla g 2);
Blattella germanica (German cockroach) calycin (Bla g 4);
Blattella germanica (German cockroach) glutathione transferase (Bla g 5);
Blattella germanica (German cockroach) troponin C (Bla g 6);
Periplaneta americana (American cockroach) Cr-PII (Per a 1);
Periplaneta americana (American cockroach) Cr-PI (Per a 3);
Periplaneta americana (American cockroach) tropomyosin (Per a 7);
Chironomus thummi thummi (midge) hemoglobin (Chi t 1-9);
Chironomus thummi thummi (midge) component III (Chi t 1.01);
Chironomus thummi thummi (midge) component IV (Chi t 1.02);
Chironomus thummi thummi (midge) component I (Chi t 2.0101);
Chironomus thummi thummi (midge) component IA (Chi t 2.0102);
Chironomus thummi thummi (midge) component II-beta (Chi t 3);
Chironomus thummi thummi (midge) component IIIA (Chi t 4);
Chironomus thummi thummi (midge) component VI (Chi t 5);
Chironomus thummi thummi (midge) component VIIA (Chi t 6.01);
Chironomus thummi thummi (midge) component IX (Chi t 6.02);
Chironomus thummi thummi (midge) component VIIB (Chi t 7);
Chironomus thummi thummi (midge) component VIII (Chi t 8);
Chironomus thummi thummi (midge) component X (Chi t 9);
Dolichovespula maculata (white face hornet) phospholipase (Dol m 1);
Dolichovespula maculata (white face hornet) hyaluronidase (Dol m 2);
Dolichovespula maculata (white face hornet) antigen 5 (Dol m 5);
Dolichovespula arenaria (yellow hornet) antigen 5 (Dol a 5);

Polistes annularies (wasp) phospholipase A1 (Pol a 1);
Polistes annularies (wasp) hyaluronidase (Pol a 2);
Polistes annularies (wasp) antigen 5 (Pol a 5);
Polistes dominulus (Mediterranean paper wasp) antigen (Pol d 1);
Polistes dominulus (Mediterranean paper wasp) serine protease (Pol d 4);
Polistes dominulus (Mediterranean paper wasp) antigen (Pol d 5);
Polistes exclamans (wasp) phospholipase A1 (Pol c 1);
Polistes exclamans (wasp) antigen 5 (Pol c 5);
Polistes fuscatus (wasp) antigen 5 (Pol f 5);
Polistes metricus (wasp) antigen 5 (Pol m 5);
Vespa crabo (European hornet) phospholipase (Vesp c 1);
Vespa crabo (European hornet) antigen 5 (Vesp c 5.0101);
Vespa crabo (European hornet) antigen 5 (Vesp c 5.0102);
Vespa mandarina (giant Asian hornet) antigen (Vesp m 1.01);
Vespa mandarina (giant Asian hornet) antigen (Vesp m 1.02);
Vespa mandarina (giant Asian hornet) antigen (Vesp m 5);
Vespula flavopilosa (yellowjacket) antigen 5 (Ves f 5);
Vespula germanica (yellowjacket) antigen 5 (Ves g 5);
Vespula maculifrons (yellowjacket) phospholipase A1 (Ves m 1);
Vespula maculifrons (yellowjacket) hyaluronidase (Ves m 2);
Vespula maculifrons (yellowjacket) antigen 5 (Ves m 5);
Vespula pennsylvanica (yellowjacket) (antigen 5Ves p 5);
Vespula squamosa (yellowjacket) antigen 5 (Ves s 5);
Vespula vidua (wasp) antigen (Ves vi 5);
Vespula vulgaris (yellowjacket) phospholipase A1 (Ves v 1);
Vespula vulgaris (yellowjacket) hyaluronidase (Ves v 2);
Vespula vulgaris (yellowjacket) antigen 5 (Ves v 5);
Myrmecia pilosula (Australian jumper ant) antigen (Myr p 1);
Myrmecia pilosula (Australian jumper ant) antigen (Myr p 2);
Solenopsis geminata (tropical fire ant) antigen (Sol g 2);
Solenopsis geminata (tropical fire ant) antigen (Sol g 4);

Solenopsis invicta (fire ant) antigen (Sol i 2);
Solenopsis invicta (fire ant) antigen (Sol i 3);
Solenopsis invicta (fire ant) antigen (Sol i 4);
Solenopsis saevissima (Brazilian fire ant) antigen (Sol s 2);
Gadus callarias (cod) allergen M (Gad c 1);
Salmo salar (Atlantic salmon) parvalbumin (Sal s 1);
Bos domesticus (cow) alpha-lactalbumin (Bos d 4);
Bos domesticus (cow) beta-lactalbumin (Bos d 5);
Bos domesticus (cow) serum albumin (Bos d 6);
Bos domesticus (cow) immunoglobulin (Bos d 7);
Bos domesticus (cow) casein (Bos d 8);
Gallus domesticus (chicken) ovomucoid (Gal d 1);
Gallus domesticus (chicken) ovalbumin (Gal d 2);
Gallus domesticus (chicken) conalbumin; A22 (Gal d 3);
Gallus domesticus (chicken) lysozyme (Gal d 4);
Gallus domesticus (chicken) serum albumin (Gal d 5);
Metapenaeus ensis (shrimp) tropomyosin (Met e 1);
Penaeus aztecus (shrimp) tropomyosin (Pen a 1);
Penaeus indicus (shrimp) tropomyosin (Pen i 1);
Todarodes pacificus (squid) tropomyosin (Tod p 1);
Haliotis Midae (abalone) antigen (Hal m 1);
Apium graveolens (celery) Bet v 1 homologue (Api g 1);
Apium graveolens (celery) profilin (Api g 4);
Apium graveolens (celery) antigen (Api g 5);
Brassica juncea (oriental mustard) 2S albumin (Bra j 1);
Brassica rapa (turnip) prohevein-like protein (Bar r 2);
Hordeum vulgare (barley) BMAI-1 (Hor v 1);
Zea mays (maize, corn) lipid transfer protein (Zea m 14);
Corylus avellana (hazelnut) Bet v 1 homologue (Cor a 1.0401);
Malus domestica (apple) Bet v 1 homologue (Mal d 1);
Malus domestica (apple) lipid transfer protein (Mal d 3);

Pyrus communis (pear) Bet v 1 homologue (Pyr c 1);
Pyrus communis (pear) profilin (Pyr c 4);
Pyrus communis (pear) isoflavone reductase homologue (Pyr c 5);
Oryza sativa (rice) antigen (Ory s 1);
Persea americana (avocado) endochitinase (Pers a 1);
Prunus armeniaca (apricot) Bet v 1 homologue (Pru ar 1);
Prunus armeniaca (apricot) lipid transfer protein (Pru ar 3);
Prunus avium (sweet cherry) Bet v 1 homologue (Pru av 1);
Prunus avium (sweet cherry) thaumatin homologue (Pru av 2);
Prunus avium (sweet cherry) profilin (Pru av 4);
Prunus persica (peach) lipid transfer protein (Pru p 3);
Sinapis alba (yellow mustard) 2S albumin (Sin a 1);
Glycine max (soybean) HPS (Gly m 1.0101);
Glycine max (soybean) HPS (Gly m 1.0102);
Glycine max (soybean) antigen (Gly m 2);
Glycine max (soybean) profilin (Gly m 3);
Arachis hypogaea (peanut) vicilin (Ar a h 1);
Arachis hypogaea (peanut) conglutin Ar a h 2);
Arachis hypogaea (peanut) glycinin (Ar a h 3);
Arachis hypogaea (peanut) glycinin (Ar a h 4);
Arachis hypogaea (peanut) (profilin Ar a h 5);
Arachis hypogaea (peanut) conglutin homologue (Ar a h 6);
Arachis hypogaea (peanut) conglutin homologue (Ar a h 7);
Actinidia chinensis (kiwi) cysteine protease (Act c 1);
Solanum tuberosum (potato) patatin (Sol t 1);
Bertholletia excelsa (Brazil nut) 2S albumin (Ber e 1);
Juglans regia (English walnut) 2S albumin (Jug r 1);
Juglans regia (English walnut) vicilin (Jug r 2);
Ricinus communis (castor bean) 2S albumin (Ric c 1);
Anisakis simplex (nematode) antigen (Ani s 1);
Anisakis simplex (nematode) paramyosin (Ani s 2);

Ascaris suum (worm) antigen (Asc s 1);
Aedes aegyptii (mosquito) apyrase (Aed a 1);
Aedes aegyptii (mosquito) antigen (Aed a 2);
Hevea brasiliensis (rubber) elongation factor (Hev b 1);
Hevea brasiliensis (rubber) 1,3-glucanase (Hev b 2);
Hevea brasiliensis (rubber) antigen (Hev b 3);
Hevea brasiliensis (rubber) component of microhelix protein complex (Hev b 4);
Hevea brasiliensis (rubber) antigen (Hev b 5);
Hevea brasiliensis (rubber) hevein precursor (Hev b 6.01);
Hevea brasiliensis (rubber) hevein (Hev b 6.02);
Hevea brasiliensis (rubber) C-terminal fragment antigen (Hev b 6.03);
Hevea brasiliensis (rubber) patafins homologue (Hev b 7);
Hevea brasiliensis (rubber) profilin (Hev b 8);
Hevea brasiliensis (rubber) enolase (Hev b 9);
Hevea brasiliensis (rubber) Mn-superoxide dismut (Hev b 10);
Ctenocephalides felis felis (cat flea) antigen (Cte f 1);
Homo sapiens (human autoallergen) antigen (Hom s 1);
Homo sapiens (human autoallergen) antigen (Hom s 2);
Homo sapiens (human autoallergen) antigen (Hom s 3);
Homo sapiens (human autoallergen) antigen (Hom s 4); and
Homo sapiens (human autoallergen) antigen (Hom s 5); and
a pharmaceutically acceptable carrier appropriate for rectal, vaginal, nasal, oral,
buccal, or mucosal delivery,
the composition being formulated for rectal, vaginal, nasal, oral, buccal, or
mucosal delivery.

35. (Currently amended) The composition of claim 34, wherein the wild-type allergen protein is found in nature in foods, venoms, or latex.
36. (Currently amended) The composition of claim 34, wherein the wild-type allergen protein is found in nature in a food selected from the group consisting of peanuts, milk, eggs, seafood, nuts, dairy products, and fruit.

37. (Withdrawn and currently amended) The composition of claim 34, wherein the wild-type allergen protein is found in nature in bee venom.

38. (Currently amended) The composition of claim 34, wherein the wild-type allergen protein is an Ara h 1, Ara h 2, or Ara h 3 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3.

39-40. (Cancelled)

41. (Currently amended) The composition of claim 34, wherein the modified allergen protein is located in the cytoplasm of the dead *E. coli*.

42. (Currently amended) The composition of claim 34, wherein the modified allergen protein is located in the periplasm of the dead *E. coli*.

43. (Currently amended) The composition of claim 34, wherein the modified allergen protein cannot be detected by antibody binding without disrupting the dead *E. coli*.

44. (Original) The composition of claim 34, wherein the composition is formulated for rectal administration.

45. (Previously presented) The composition of claim 34, wherein the dead *E. coli* was heat-killed.

46. (Previously presented) The composition of claim 34, wherein the dead *E. coli* was killed by chemical treatment.

47. (Previously presented) The composition of claim 44, wherein the dead *E. coli* was killed using a chemical selected from the group consisting of iodine, bleach, ozone, and alcohol.

48. (Previously presented) The composition of claim 34, wherein the composition is formulated for mucosal administration.

49. (Previously presented) The composition of claim 34, wherein the composition is formulated for oral administration.